DJO GLOBAL

510(k) Summary

APR 10 2014

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K132284

Submitted by:

DJO, LLC
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Date Summary Prepared: July 19, 2013

Trade Name: Vectra Neo Clinical Therapy System

Common/Usual Name: Vectra Neo Clinical Therapy System

Classification Name:

21 CFR 890.5500	Infrared lamp
21 CFR 890.5850	Powered muscle stimulator
21 CFR 890.5860	Ultrasound and Muscle stimulator
21 CFR 882.5890	TENS for pain relief
21 CFR 882.5050	Biofeedback device
21 CFR 882.5810	External functional neuromuscular stimulator
Unclassified	Interferential current stimulator

Product Code:

ILY	Infrared lamp
IPF	Powered muscle stimulator
IMG	Ultrasound and muscle stimulator
GZJ	Transcutaneous electrical nerve stimulator for pain relief
HCC	Biofeedback device
GZI	External functional neuromuscular stimulator
LIH	Interferential current therapy

Regulatory Class: Class II

Panels: 89 – Physical Medicine
84 – Neurology

Predicate Device(s): Vectra Genisys Laser System (Intelect XT Laser System) (K040662)
Vectra Genisys (K062354)

Device Description:
The Vectra Neo Clinical Therapy System is an electrotherapy product offering clinicians a modular design of muscle stimulation, ultrasound, laser and biofeedback modalities in one combination device. The Vectra Neo Clinical Therapy System is designed to give the most treatment options in one compact and integrated package.

Clinicians have a variety of choices to best suit the needs of their individual practice. Below is an overview of the system choices/features.

The electrotherapy mode offers one of the largest selections of multiple waveforms cleared to market by FDA. The numeric pain scales can be recorded with the patient data management system. The therapy system cart provides three storage drawers to conveniently house clinical essentials. The leadwire management system allows for easy, quick access in an uncluttered arrangement.

The electrotherapy module offers 12 waveforms: Interferential, Premodulated (IFS), Asymmetrical Biphasic (TENS), Microcurrent, VMS, VMS Burst, VMS FR, Russian, High Voltage Pulsed Current, Symmetrical Biphasic (TENS), Direct Current, and HAN (TENS). The Vectra Neo Clinical Therapy System allows to sequence these waveforms for ease of use.

The Neo ultrasound module is dual frequency (1 MHz and 3.3 MHz) with selectable duty cycles of 10%, 20%, 50% and 100%, low BNR (5.0:1) (FDA method of measurement), pulse frequency 100Hz and selectable pulse durations of 1 mSec, ±20%; 2 mSec, ±20%; 5 mSec, ±20%.

The following ultrasound applicators are provided with the Vectra Neo Clinical Therapy System:

Model Number	Description	BNR (FDA method)	Standard Deviation (BNR)	ERA (cm^2)	ERA Limits (cm^2)		Beam Type (Pattern)	Frequency (MHz)	Number of Crystals	Max. Output Power (W)
					High	Low				
27333	1 cm^2 ultrasound applicator	5:1	1	0.9	1	0.4	Collimating	3.3	1	1.5
27334	2 cm^2 ultrasound applicator	5:1	1	1.8	2	1.4	Collimating	1.0 and 3.3	1	3.0

Model Number	Description	BNR (FDA method)	Standard Deviation (BNR)	ERA (cm^2)	ERA Limits (cm^2)		Beam Type (Pattern)	Frequency (MHz)	Number of Crystals	Max. Output Power (W)
					High	Low				
27335	5 cm^2 ultrasound applicator	5:1	1	4.0	5	3	Collimating	1.0 and 3.3	1	6.0
27336	10 cm^2 ultrasound applicator	5:1	1	8.5	10	7	Collimating	1.0 and 3.3	1	15.0

The laser therapy module is indicated for the temporary increase in local blood circulation, temporary relief of minor muscle and joint aches, pains and stiffness, temporary relaxation of muscles, temporary relief of muscle spasms, temporary relief of minor pain and stiffness associated with arthritis.

The sEMG biofeedback module provides two channels of surface EMG. Feedback can be stored onto a USB Thumb Drive. The sEMG features a clinician chosen trigger point that activates therapeutic stimulation. The sEMG feature is often used to treat stroke patients and for muscle re-education.

Online guided assistance is provided through Clinical Protocol Setup and On-Screen Indications to help guide therapy selections for electrotherapy waveform rationale, parameter selections, electrode placement images, laser and ultrasound applicator recommendations.

Combination electrotherapy is used for the management of pain and muscle spasm. All functions of 1 or 3.3 MHz Ultrasound can be combined with Interferential, Premodulated (IFS), Asymmetrical Biphasic (TENS), VMS, VMS Burst, VMS FR and High Voltage Pulsed Current.

Intended Use:
Vectra Neo Clinical Therapy System is indicated for:

For VMS-(Pulsed Mode, Burst Mode or FR Mode), Russian, Monophasic Hi-Volt (NMES) & Interferential and Premodulated (IFS)

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis

Additionally for Microcurrent, Interferential, Premodulated (IFS), VMS-(Pulsed Mode, Burst Mode or FR Mode), Asymmetrical Biphasic (TENS), Symmetrical Biphasic (TENS), and HAN

- Symptomatic relief or management of chronic, intractable pain

- Post-traumatic acute pain
- Post-surgical acute pain

For DC Continuous Mode

- Relaxation of muscle spasm

For FES

- Stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait

For EMG triggered Stim

- Stroke rehab by muscle re-education
- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion

For EMG

- To determine the activation timing of muscles for:
  - Retraining of muscle activation
  - Coordinating of muscle activation
- An indication of the force produced by muscle for control and maintenance of muscle contractions
  - Relaxation muscle training
  - Muscle re-education

For Ultrasound

Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as:

- Relief of pain, muscle spasms and joint contractures
- Relief of pain, muscle spasms and joint contractures that may be associated with :
  - Adhesive capsulitis
  - Bursitis with slight calcification
  - Myositis
  - Soft tissue injuries
  - Shortened tendons due to past injuries and scar tissues
- Relief of sub-chronic and chronic pain and joint contractures resulting from:
  - Capsular tightness
  - Capsular scarring

For Infrared Lamp (laser)
To provide topical heating for the following:

- Temporary increase in local blood circulation
- Temporary relief of minor muscle and joint aches, pains and stiffness
- Relaxation of muscles
- Temporary relief of muscle spasms
- Temporary relief of minor pain and stiffness associated with arthritis

Indication for Use Comparison to Predicate Devices:

- Vectra Genisys (K062354) – primary predicate

The Vectra Neo Clinical Therapy System has the same Indications for Use as the Vectra Genisys for the following types of treatment:

  - VMS-(Pulsed Mode, Burst Mode or FR Mode), Russian, Monophasic Hi-Volt (NMES) & Interferential and Premodulated (IFS)
  - Additionally for Microcurrent, Interferential, Premodulated (IFS), VMS-(Pulsed Mode, Burst Mode or FR Mode), Asymmetrical Biphasic (TENS), and Symmetrical Biphasic (TENS) and HAN
  - For FES
  - For DC Continuous Mode
  - For EMG
  - For EMG triggered Stim
  - For Ultrasound

- Vectra Genisys Laser System (Intelect XT Laser System) (K040662) – secondary predicate

The Vectra Neo Clinical Therapy System has the same Indications for Use as the Vectra Genisys Laser System (Intelect XT Laser System)

  - For Infrared Lamp (laser)

Technological Comparison to Predicate Devices:
The Vectra Neo Clinical Therapy System is technologically equivalent to Vectra Genisys (K062354) and Vectra Genisys Laser System (Intelect XT Laser System) (K040662) with respect to technical and performance characteristics.

The Vectra Neo Clinical Therapy System has the same indications for use and the same fundamental technology as the two predicate devices. It is intended to be used by the same target population and in the same clinical environments. The Vectra Neo Clinical Therapy System simply combines the functionality of the two predicates into one modular, adaptable device and has been upgraded with more modern components and has been engineered to meet FDA-recognized international consensus standards.

Some of the minor differences include: the user interface has been simplified from having 16 buttons to 2 buttons and a touchscreen, additional FDA recognized consensus standards have been conformed to, and some outputs have been modified slightly. These differences are minimal and do not affect the device's performance or efficacy. With respect to safety, these minor differences could only improve device safety. Additionally, bench performance testing has demonstrated that the Vectra Neo Clinical Therapy System has the same waveforms and other outputs as the predicate devices and has passed all verification and validation activities.

All differences noted above do not raise new issues of safety and effectiveness.

Performance Testing:

- The device's software has been validated in accordance with the requirements set forth in the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices (May 11, 2005). The software validation tests demonstrated that the software version meets its design requirements.

- A Usability Study was conducted to validate the usability of the Vectra Neo Clinical Therapy System. The results of the Summative Validation support the instructions for successfully using the device as intended. The result of the Human Factors and Usability Study substantiates the acceptability of the risks identified during the risk assessment activities.

- The Vectra Neo Clinical Therapy System was tested and found to comply with the following standards:
  - IEC 60601-1 for basic safety and essential performance
  - IEC 60601-1-2 for electromagnetic compatibility
  - IEC 60601-2-5 for safety of ultrasonic physiotherapy equipment
  - IEC 60601-2-10 for performance of nerve and muscle stimulators
  - IEC 60601-2-22 for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
  - IEC 60601-2-57 for basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use (Radiology)
  - IEC 60825-1 for safety of laser products

Biocompatibility:

The Vectra Neo Clinical Therapy System has no direct or indirect contact with the patient. The table below identifies accessories that have direct contact with the patient at the treatment site, the material in contact with the patient, reference to the predicateand if applicable, reference devices. For new accessories, evaluation for biocompatibility is in accordance ISO 10993-1:2009 – Annex C, Suggested Procedure for Literature Review. The conclusion of these evaluations , as well as reference to the predicate and any associated reference devices, indicate that all materials selected are considered safe and effective for the intended use.

Accessory	Patient Contacting Material	Predicate	Reference Device	Biocompatibility Route
Electrodes	Hydrogel	Identical to predicate (K062354)	K900519 K874469 K852267 K970426	n/a
Ultrasound Gel	Conductive gel	Identical to predicate (K062354)	K955246	n/a
Hivolt Probe	Cellulose Pad Polyester	Identical to predicate (K062354)	n/a	n/a
Ultrasound Applicators	No direct patient contact (see Ultrasound Gel)	Identical to predicate (K062354)	n/a	n/a
Laser Applicators	Aluminum Chrome Copper-Nickel Polycarbonate	Identical to predicate (K040662)	n/a	n/a
Laser Safety Glasses	Nylon	Identical to predicate (K040662)	n/a	n/a
Patient Remote	Polycarbonate/ABS Silicone	NEW	n/a	ISO 10993-1:2009 – Annex C, Suggested Procedure for Literature Review, which included a comparison to the same patient contacting materials used for the predicate device (K062354) remote

Conclusion:

Based on the performance testing and the supporting documentation, it can be concluded that the Vectra Neo Clinical Therapy System is safe, effective and substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 10, 2014

DJO, LLC
Lorri Trotter
Regulatory Affairs Manager
1430 Decision Street
Vista, CA 92081

Re: K132284
Trade/Device Name: Vectra Neo Clinical Therapy System
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF; IMG; GZJ; HCC; GZI; LIH; ILY
Dated: March 6, 2014
Received: March 7, 2014

Dear Ms. Trotter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Felipe Aguel -S

for Carlos Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K132284

Device Name
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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.04.10 15:34:06 -04'00'

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